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PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(MBHB Case No. 02-728-B (400.120))

In re Application of:

McSwiggen, James A.

Serial No.: 10/607,933

Group Art Unit: 1645

Filed: July 27, 2003

Examiner: Not Assigned

For: RNA Interference Mediated Treatment
Of Alzheimer's Disease Using Short
Interfering Nucleic Acid (siNA)

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

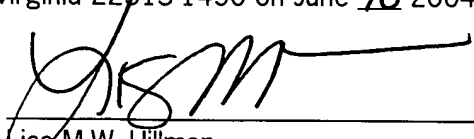
Sir:

TRANSMITTAL LETTER

In regard to the above identified application:

1. We are transmitting herewith the attached papers for the above identified new patent application:
 - ☒ Supplemental Information Disclosure Statement;
 - ☒ Supplemental Information Disclosure Statement (IDS) PTO-1449 Form;
 - ☒ Copies of IDS Citations for S/N 10/607,933 (Total 2 U.S. patents, 7 foreign patents and 15 other documents); and
 - ☒ Return Receipt Postcard.
2. With respect to additional fees, no additional fee is required.
3. GENERAL AUTHORIZATION: Please charge any additional fees or credit overpayment to Deposit Account No. 13-2490. A duplicate copy of this sheet is enclosed.
4. CERTIFICATE OF MAILING UNDER 37 CFR § 1.8: The undersigned hereby certifies that this Transmittal Letter and the paper, as described in paragraph 1 hereinabove, are being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450 on June 10 2004.

By :



Lisa M.W. Hillman
Reg. No. 43,673

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. Section 1.97 - 1.99, the Applicant wishes to make the following references of record in the above-identified application. This Supplemental Information Disclosure Statement is in compliance with the continuing duty of candor as set forth in 37 C.F.R. Section 1.56. Copies of the cited references are enclosed. These references are also listed on the enclosed PTO Form 1449.

As this Information Disclosure Statement is being submitted after receipt of a foreign search report, a copy of the search report is attached herewith.

In the judgment of the undersigned, portions of the listed references may be material to the Examiner's consideration of the presently pending claims. This statement is not a representation that the listed references have effective dates early enough to be "prior art" within the meaning of 35 U.S.C. Section 102 or Section 103.

Applicants do not believe any fee is due with this submission. If this belief is in error and the Patent Office determines that the fee prescribed in the relevant portion of 37 C.F.R. Section 1.97 is applicable, the undersigned attorney by his signature hereby authorizes any such fee to be debited from Deposit Account 13-2490.

U. S. PATENTS

1. Robinson et al., U.S. Patent No. 5,814,620, issued September 29, 1998
2. Fire et al., U.S. Patent No. 6,506,559, issued January 14, 2003

FOREIGN PATENT DOCUMENTS

- * Kreutzer et al., Canadian Patent No. 2,359,180, issued August 3, 2000
3. Gillespie et al., International Application No. WO 90/14090, published November 29, 1990
4. Agrawal et al., International Application No. WO 94/01550, published January 20, 1994
- * Fire et al., International Application No. WO 99/32619, published July 1, 1999
5. Graham et al., International Application No. WO 99/40-20, published September 30, 1999
- * Plaetinck et al., International Application No. WO 00/01846, published January 13, 2000
6. Gurney et al., International Application No. WO 00/17369, published March 30, 2000
- * Li et al., International Application No. WO 00/44914, published August 3, 2000
7. Jen Sheen, International Application No. WO 00/49035, published August 24, 2000
- * Zernicka-Goetz et al., International Application No. WO 01/36646, published May 21, 2001
8. Mushegian et al., International Application No. WO 01/96584, published December 20, 2001
9. Bennett et al., International Application No. WO 02/22636, published March 21, 2002

OTHER DOCUMENTS

10. Basi et al., "Antagonistic Effects of β -Site Amyloid Precursor Protein-cleaving Enzymes 1 and 2 on β -Amyloid Peptide Production in Cells*," *The Journal of Biological Chemistry*, 278, 31512-31520 (2003)
11. Edbauer et al., "Resenilin and nicastrin regulate each other and determine amyloid β -peptide production via complex formation," *PNAS*, 99, 8666-8671 (2002)

- * Elbashir et al., "Duplexes of 21-nucleotide RNAs mediate RNA interference in cultured mammalian cells," *Nature* 411:494-498 (2001)
- * Elbashir et al., "Functional Anatomy of siRNAs for Mediating Efficient RNAi in *Drosophila Melanogaster* Embryo Lysate," *The EMBO Journal* 20:6877-6888 (2001)
- * Fire et al., "Potent and Specific Genetic Interference by Double-Stranded RNA in *Caenorhabditis Elegans*," *Nature* 391:806-811(1998)
- 12. Futami et al., "Induction of apoptosis in HeLa cells with siRNA expression vector targeted against bcl-2," *Nucleic Acids Research Supplement*, 251-252 (2002)
- 13. Haniu et al., "Characterization of Alzheimer's β -Secretase Protein BACE," *The Journal of Biological Chemistry*, 275, 21099-21106 (2000)
- 14. Hussain et al., "Identification of a Novel Aspartic Protease (Asp 2) as β -Secretase," *Molecular and Cellular Neuroscience*, 14, 419-427 (1999)
- 15. International Search Report for PCT/US03/05028 mailed October 17, 2003
- 16. International Search Report for PCT/US03/05346 mailed October 17, 2003
- 17. International Search Report for PCT/US03/04710 mailed November 18, 2003
- 18. Koike et al., "Thimet Oligopeptidase Cleaves the Full-Length Alzheimer Amyloid Precursor Protein at a β -Secretase Cleavage Site in COS Cells," *J. Biochem.*, 126, 235-242 (1999)
- 19. Leirdal et al., "Gene silencing in mammalian cells by preformed small RNA duplexes," *Biochemical and Biophysical Research Communications*, 295, 744-748 (2002)
- 20. Lin et al., "A Novel mRNA-cRNA Interference Phenomenon for Silencing bcl-2 Expression in Human LNCaP Cells," *Biochemical and Biophysical Research Communications*, 281, 639-644 (2001)

21. Lin et al., "Human aspartic protease memapsin 2 cleaves the β -secretase siet of β -amyloid precursor protein," *PNAS*, 97, 1456-1460 (2000)
22. Noviello et al., "Autosomal Recessive Hypercholesterolemia Protein Interacts with and Regulates the Cell Surface Level of Alzheimer's Amyloid β Precursor Protein*," *The Journal of Biological Chemistry*, 278, 31843-31847 (2003)
23. Tuschl et al., "Small Interfering RNAs: A Revolutionary Tool for Analysis of Gene Function and Gene Therapy," *Molecular Interventions*, 295, 3, 158-167 (2002)
- * Tuschl et al., "Targeted mRNA Degradation by Double-Stranded RNA In Vitro," *Genes & Development* 3191-3197 (1999)
- * Vassar et al., " β -Secretase Cleavage of Alzheimer's Amyloid Precursor Protein by the Transmembrane Aspartic Protease BACE," *Science* 286:735-741 (1999)
24. Yan et al., "Membrane-anchored Aspartyl Protease with Alzheimer's Disease β -Secretase Activity," *Nature* 402:533-537 (1999)

Respectfully submitted,

McDonnell Boehnen Hulbert & Berghoff LLP

Date: June 10, 2004

By: 

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FORM PTO-1449 (Rev. 2-32)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. 02-728-B (400.120)	Serial No. 10/607,933
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Applicant: McSwiggen et al.	
		Filing Date: July 27, 2003	Group: 1645



U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	1.	5,814,620	09/29/98	Robinson et al.			
	2.	6,506,559	01/14/03	Fire et al.			

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
	*	2,359,180	08/03/00	CA (Kreutzer et al.)				
	3.	90/14090	11/29/90	WO (Gillespie et al.)				
	4.	94/01550	01/20/94	WO (Agrawal et al.)				
	*	99/32619	07/01/99	WO (Fire et al.)				
	5.	99/49029	09/30/99	WO (Graham et al.)				
	*	00/01846	01/13/00	WO (Plaetinck et al.)				
	6.	00/17369	03/30/00	WO (Gurney et al.)				
	*	00/44914	08/03/00	WO (Li et al.)				

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication.

FORM PTO-1449
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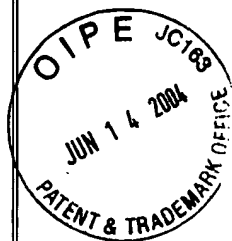
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1645

7.	00/49035	08/24/00	WO (Jen Sheen)				
*	01/36646	05/21/01	WO (Zernicka-Goetz et al.)				
8.	01/96584	12/20/01	WO (Mushegian et al.)				
9.	02/22636	03/21/02	WO (Bennett et al.)				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc).

10.	Basi et al., "Antagonistic Effects of β -Site Amyloid Precursor Protein-cleaving Enzymes 1 and 2 on β -Amyloid Peptide Production in Cells*," <i>The Journal of Biological Chemistry</i> , 278, 31512-31520 (2003)
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14.	Hussain et al., "Identification of a Novel Aspartic Protease (Asp 2) as β -Secretase," <i>Molecular and Cellular Neuroscience</i> , 14, 419-427 (1999)
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	*	Vassar et al., "β-Secretase Cleavage of Alzheimer's Amyloid Precursor Protein by the Transmembrane Aspartic Protease BACE," <u>Science</u> 286:735-741 (1999)
	24.	Yan et al., "Membrane-anchored Aspartyl Protease with Alzheimer's Disease β-Secretase Activity," <u>Nature</u> 402:533-537 (1999)

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